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Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith are copies of the applications for patent term extension for U.S. Patent Nos. 6,159,229; 5,800,509; 5,891,190; 6,309,402; 5,879,382; 5,292,331; 5,536,965; and 6,344,053. The applications were filed on November 26, 2003, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to Mary C. Till at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Kery A. Fries

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Michael J. Jaro, Esq.
Chief Patent Counsel
Medtronic Vascular
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Santa Rosa CA 95403

RE: S8 Over-the-Wire System (Driver® Stent Delivery System)
FDA Docket Nos. 2006E-0206, 2004E-0300; 2004E-0301; 2004E-0302; 2004E-0303; 2004E-0304; 2004E-0306; 2004E-0426